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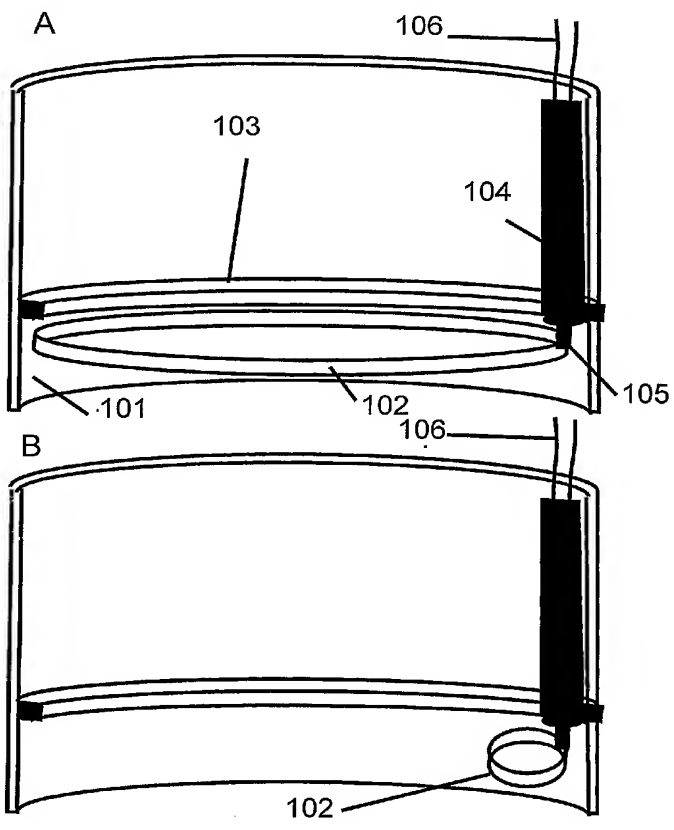
(54) Title: VASCULAR CLOSURE METHODS AND APPARATUSES



(57) Abstract: A vascular closure device comprised of a sheath-delivered cincture or noose-like device or knot comprised of suture, wire, or other suitable materials, that is placed on the external surface of a puncture wound, and closed. The vascular closure cincture is delivered by a sheath, and after closing is left resident on the external surface of a tissue puncture wound.

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Vascular Closure Methods and Apparatuses

Technical Field

[0001] The present invention relates to methods and apparatuses for closing punctures and apertures in human and animal tissue and to methods and apparatuses for inserting such an apparatus into such tissue to perform such closure functions.

Background Art

[0002] This application is related to U.S. provisional application 60/711,279, filed 8/25/2005, and U.S. utility application 11/316,775, filed 12/23/2005, each of which is incorporated herein by reference. During angiography and related procedures, catheters are inserted through an incision or puncture in the skin and underlying tissues to access an artery or vein, typically in the groin, neck, or subclavian areas of a patient. The catheter can be inserted through a puncture in the blood vessel and guided to the desired site to perform interventional procedures such as angiography, angioplasty, plaque removal, and infusion of a therapeutic substance. After the procedure is completed and the catheter is removed from the patient, the access hole must be closed to prevent massive hemorrhage. This is conventionally achieved by applying pressure over the blood vessel manually and then by applying a pressure bandage, compressive weight, or clamp device. With conventional methods, the rate of post-puncture hemorrhage is high, which causes considerable complications. This complication is exacerbated by the concomitant use of anticoagulant medications such as heparin or warfarin and by antiplatelet drugs, which are commonly used to treat vascular disease.

[0003] Sutures have been used to close access puncture wounds in blood vessels. US05613974 describes a device and method for applying sutures to a vascular puncture. US2004/0093027A1 describes barbed suture-like material that apposes the puncture site. US 2005/0121042 A1 describes a device and method for applying suture to a vascular puncture. Difficulties with these methods include the large number of steps necessary to deploy the needles, capture the suture, withdraw the suture, tie the knot, and cut the suture. In addition, the hole in the blood vessel is often widened by insertion of the instrument, and the suture remains intravascularly on the endothelial surface, and thus can be a nidus for thrombus or intravascular mural hyperplasia with later spontaneous and catastrophic closure of the vessel.

[0004] Extravascular plugs have also been proposed for closure of vascular punctures. US05254105 and US05330445 describe an extravascular plug which is slid down the external surface of the catheter or introducer and is placed into the puncture site in this manner. US05643318 relates to a similar device that has its own vessel locator device. US22022822A1 and US2004/0158287A1 describe an extravascular plug that is delivered with a specialized system. US24215232A1 describes an extravascular plug with an intravascular anchor set with a sheath with a detection port. US2005/0085855A1 describes an extravascular collagen plug, held in place with an intravascular anchor, and a device that locks over a piece of suture. US05906631 describes a plug made of hydrophilic material. US06126675 describes an intravascular anchor and a bioabsorble extravascular plug. US06623509 describes a bioabsorbable plug. US06296657 and US06743195 describe an inflatable balloon that puts pressure on the puncture site. US06569185 describes an injectable vascular plug. US06663655 describes a plug that screws in the puncture tract. US2004/0143290 A1 describes a

combination of an intraluminal balloon and injectable sealant. Disadvantages to these methods are related to the high likelihood of thrombosis associated with the intravascular plug or anchor, and the presence of collagen or other bioabsorble materials which cause inflammation, activate the clotting cascade, and increase the likelihood of thrombosis, which, in an arterial system, is catastrophic.

[0005] Vascular patches have also been used for repairing blood vessels, but usually only for large areas of damage. US05100422 describes a vascular patch that is sutured to the external surface of the damaged blood vessel. US05100422 describes a vascular patch achieved by instilled adhesives and the device for doing such. These are generally impractical for catheter-based methods. US06248124 and US05507744 describe devices and methods that use electrocautery for sealing vascular punctures. This also requires a complicated device, and perforation and thrombosis are very real possibilities.

[0006] Vascular clips or staples delivered through a catheter device have also been proposed. These devices have penetrating members that bring the edges of the tissue together. US06695867 describes a clip or staple that is delivered by a specialized device. US06749622 describes a number of different clips with sharpened barbs or ends that include both intra- and extravascular portions, made of metal with memory characteristics. US05861005 describes an arterial staple that is delivered with a specialized device. US05919207 describes a stapling system based on long hooked wires that appose the surfaces, with a small staple gun to close the lesion. US06022372 describes a similar staple gun. US06296657, US06663655, and US06749621 describe a clip that is external to the vessel, but clips the two sides of the puncture together, and a device for achieving such. US 5782861 and US 5964782 describe clip devices composed of two or more prongs or hooks that, depending on the direction of the prongs, can clip together the puncture site from the intra- or extravascular position, through the use of a collar which forces the prongs together or other mechanisms. These clip devices are composed of thick semi-rigid material,and can be placed only with a specialized instruments, and because of the rigidity have great potential to injure or cut the blood vessel. Disadvantages of these clip devices in general include difficulty in retrieving the device if misplaced, excessive manipulation required, the thickness of the clip material which tends to cut or shear the blood vessel, the large forces that must be used to curve the staples and fix the clips, the increased possibility of tearing the blood vessel, and the general lack of control of the forces being applied to the blood vessel.

[0007] Accordingly, there is a need for methods and apparatuses that are suitable for closure of vascular punctures or other openings, and that do not suffer from the drawbacks of conventional approaches.

Disclosure of Invention

[0008] The present invention provides methods and apparatuses that are suitable for closure of vascular punctures or other openings, and that do not suffer from the drawbacks of conventional approaches.

[0009] The present invention comprises a tissue closure device, comprised of a cincture, noose, or snare of suture or other material, which can be tightened over a puncture wound, closing the wound from the external surface of this wound.

[0010] The present invention also comprises methods for closing tissue openings, comprising a) passing a device while in a first compressed condition through a sheath that penetrates the proximal surface of the tissue; b) extruding the device from the sheath into space beyond the proximal surface of the tissue such that the device assumes an expanded configuration; c) manipulating the device such that tissue

engagement elements of the device engage the tissue; d) putting traction on the device, everting the edges of the opening, e) placing another sheath over the device, which sheath contains a cincture or noose which when dislodged or tightened from the sheath first engages, and then closes the opening by closing the cincture, h) removing the traction device and overlying sheaths, resulting in a cincture closure of the wound. The sheath can comprise various shapes and materials, as examples a solid walled or porous walled cylinder or other shape, or a plurality of guide rods or bars mounted relative to each other.

[0011] The present invention can provide a cincture or noose-like device comprising fine, strong, flexible material that after delivery ties off or closes a puncture wound. The device can be viewed as analogous in structure and design as a snare, noose, or cincture, and is similar in design to closure methods used for sacks and garbage bags. As a catheter is withdrawn from an opening, a traction or gripping device can be pulled against the interior of a blood vessel (or other tissue having an opening to be closed) and hooks or grasping features that are part of the traction or gripping device seize and/or penetrate the interior of the vessel wall. The traction or gripping device can be adapted to apply minimal shear force to the vessel wall, for example by forming the device with a plurality of flexible the members with minimal cutting surfaces. A larger sheath containing a cincture can be placed over the traction sheath, and while placing traction on the gripping members, the cincture can be closed about the everted wound edges, closing the wound. The traction device can be removed, resulting in complete closure of the puncture wound. If there is no blood leakage through the closure and the cincture device is properly positioned and stable, then the guidewire can be removed and the retaining suture or string loop cut, resulting is complete and rapid closure, which can then heal. Alternatively, the guidewire can be removed first, and the traction device removed last.

[0012] Since the present invention brings the puncture edges together and the cincture remains on the external surface of the blood vessel, there is true blood vessel healing with little endothelial disruption, reducing the chances of thrombosis or intimal hyperplasia. The device can be supplied in different diameters (e.g., french) to accommodate different sizes of catheters and different sizes of puncture holes.

Brief Description of Drawings

[0013] The invention is explained by using embodiment examples and corresponding drawings, which are incorporated into and form part of the specification.

Figure 1(a,b) is a schematic illustration of a vascular closure device according to the present invention.

Figure 2(a,b) is a schematic illustration of a vascular closure device according to the present invention.

Figure 3(a,b) is a schematic illustration of a vascular closure device according to the present invention.

Figure 4(a,b) is a schematic illustration of a gripper and sheath according to the present invention.

Figure 5(a,b,c,d) is a schematic illustration of eversion of the edges of a tissue opening, and closure of the opening, according to the present invention.

Figure 6(a,b,c,d) is a schematic illustration of eversion of the edges of a tissue opening, and closure of the opening, according to the present invention.

Figure 7(a,b,c,d,e,f,g) is a schematic illustration of steps in a method of closing a tissue opening according to the present invention.

Figure 8 is a schematic illustration of several cinctures suitable for use in the present invention.

Modes for Carrying Out the Invention, and Industrial Applicability

[0014] The present invention provides apparatuses and methods for closing a vascular puncture wound or any tissue aperture, for example those resulting from the insertion of a vascular catheter or surgical instrument, trauma or disease. The present invention embraces both apparatus and method aspects of devices for closing a vascular puncture, and the methods for delivering such a device. Example embodiments of a delivery device according to the present invention are shown in Figures 1, 2, 3, and 4. The descriptions refer to "vessels" for convenience; the present invention is applicable to facilitate closure of various types of tissue openings. Example embodiments of a gripping device according to the present invention are shown in Figures 4, 5, and 6. Methods for placing the device are shown in Figure 7. Example embodiments of the closure cincture are shown in Figure 8.

[0015] Figure 1(a,b) is a schematic illustration of a cincture delivery sheath 101 according to the present invention. Figure 1(a) shows the cincture 102 before contraction, and Figure 1(b) shows the cincture 102 after contraction. The interior wall of the delivery sheath 101 delivers a cincture 102, which can be held in place in the sheath 101 by a retention structure 103. The retention structure 103 can prevent the cincture 102 from malpositioning and from prematurely contracting. The cincture 102 can be held by fingers from the retention structure 103, can be sufficiently rigid to not readily change position, or can be temporarily held in place by a wax-like or other semi-solid biocompatible material that will give way with contraction of the cincture 102. The cincture 102 can be attached to a retractable suture loop 106 which is contained in a lumen 104, shown in the figure as a cylindrical structure. The lumen 104 can comprise a narrowed portion 105 that permits the cincture material to pass, but prevents a tightening feature (e.g., a functional slipknot) from passing. Thus when the suture loop 106 is pulled, the radius of the cincture 102 becomes narrower. When the suture loop 106 is pulled in its entirety, the cincture loop 102 completely closes, effecting closure of the opening (e.g., a puncture wound).

[0016] Figure 2(a,b) is a schematic illustration of a cincture delivery sheath 201 according to the present invention. The embodiment of Figure 2 comprises a cincture 202 external to a sheath 201. Figure 2(a) shows the cincture 202 before contraction; Figure 2(b) shows the cincture 202 after contraction. The wall of the delivery sheath 201 delivers an external cincture 202 which is held in place on the sheath by a retention structure 203, which prevents the cincture 202 from malpositioning or premature tightening. The cincture 202 can be held by fingers from the retention structure 203, can be sufficiently rigid to not readily change position, or can be temporarily held in place by a wax-like or other semi-solid biocompatible material that will give way with contraction of the cincture 202. The cincture 202 is attached to a retractable suture loop 206 which is contained in a lumen 204, here shown as a cylindrical structure. The lumen 204 can comprise a portion with a reduced cross-section or similar feature that allows cincture material or suture to pass, but prevents a tightening feature (e.g., a functional slip-knot) from passing. Thus when the suture loop 206 is pulled, the cincture 202 is pulled down the external surface of the sheath 201, and the radius of the cincture 202 becomes narrower. When the suture loop 206 is pulled in its entirety, the cincture loop 202 completely closes, effecting closure of the opening.

[0017] Figure 3(a,b) is a schematic illustration of a cincture delivery sheath 301 according to the present invention The embodiment of Figure 3 comprises a cincture 302 external to the sheath 301. Figure 3(a) shows the cincture 302 before contraction; Figure 3(b) shows the cincture 302 after contraction. The wall

of the delivery sheath 301 delivers an external cincture 302 which can be held in place on the sheath 301 by a retention structure 303. The retention structure 303 can comprise, as examples, fingers projecting from the sheath 301, a second sheath engaged with the first sheath 301, or a wax-like or other semi-solid biocompatible material that will give way with contraction of the cincture. The cincture 302 comprises a resilient or memory material that it is self-contracting after removal from the sheath 301. The cincture can be attached to a retractable suture loop 306 which is contained in a lumen 304, here shown as a cylindrical structure. The retractable suture loop 306 can be used to pull the cincture 203 past the end of the sheath 301. If the retention structure 303 comprises a second sheath, or otherwise has the ability to move the cincture past the end of the sheath 301, then the suture loop 306 might not be necessary (although it can still be useful for retrieving misplaced cinctures). When the self contracting cincture 302 is moved past the end of the sheath 301, by action of the suture loop 306 or the retention device 303, the cincture contracts, reducing its radius and closing the opening in the tissue.

[0018] Tissue edge eversion can be accomplished with a gripper or everter device such as that shown in Figure 4. Figure 4(a,b) is a schematic illustration of a gripper and sheath, shown in section to illustrate gripper tines disposed within the sheath 403. Gripper tines 402 (two in the figure, although more or fewer can be used) are disposed within a sheath 403 in Figure 4a. The sheath 403 constrains the gripper tines 402 to fit within the walls of the sheath 403. In Figure 4b, the gripper tines 402 have moved past the end of the sheath 403. Absent the constraining influence of the sheath 403, the gripper tines 402 have curved outwards from the sheath and upwards along the direction of the sheath. The gripper tines can grip the edges of a tissue opening, and evert them when the gripper tines or the corresponding sheath is pulled away from the tissue.

[0019] Figure 5(a,b,c,d) is a schematic illustration of eversion of the edges of a tissue opening using a device such as that described in relation to Figure 4, and closure of the opening using a cincture such as those described above. Figure 5a shows the device with the gripper tines 502 constrained in a sheath 503. A guidewire 504 passes through the sheath 503. The sheath 503 is resident in the tissue opening, passing through the proximal vessel wall 506 but not reaching the distal vessel wall. Figure 5b shows the device after the gripper tines 502 have been extended past the end of the sheath 503. The gripper tines 502, have curved away from the sheath 503 and back along the direction of the sheath 503, penetrating the proximal vessel wall 506. Traction applied to the gripper tines 502 and sheath 503 everts the edges of the opening, as shown in Figure 5c. The edges are held by the gripper tines 702 so that the proximal vessel wall 706 is pulled when the gripper tines 702 and sheath 703 are pulled. The everted edges of the tissue opening are now ready for deployment of a cincture like those described herein, shown in Figure 5(d).

[0020] Figure 6(a,b,c,d) is a schematic illustration of a method of everting the edges of a tissue opening, using a device like that described in relation to Figure 4 and closing the opening with a cincture such as those described herein. The gripper sheath 601 with memory tines 602 is introduced into a blood vessel 603 over a guidewire 604. After introduction, the tines 602 are extended, which then grip the proximal tissue 603. Traction (pulling) is placed on the gripper sheath 602, everting the wound edges 603. A cincture 609 can be placed over the everted wound edges, closing the puncture wound around the guidewire 604. If there is not bleeding, then the guidewire 604 and sheath 601 can be removed.

[0021] Figure 7(a,b,c,d,e,f,g) is a schematic illustration of steps in a method of closing a tissue opening according to the present invention. In Figure 7a, a gripper sheath 701, for example a gripper sheath like that described in relation to Figure 4, is present within an opening in tissue, near a proximal wall 706 and edges 705 of an opening therethrough, but not near a distal wall 707. The gripper sheath 701 constrains gripper tines 702 disposed within the gripper sheath 701. In Figure 7b, the gripper tines 702 have been extended past the end of the gripper sheath 701, curving back and engaging the edges 705 of the tissue opening. In Figure 7c, the gripper sheath 701 has been pulled away from the tissue. The edges 705 of the opening, held by the gripper tines 702, have been everted by the motion of the gripper sheath 701. The gripper tines can reside within sublumens within or on the sheath, or a single shared lumen in the sheath. The number of gripper tines can be 2 or greater, and they can be directed away from the lumen or cross over each other. They can penetrate the blood vessel wall, but need not fully penetrate the vessel, instead simply gripping the vessel wall so it can be everted. The tines can be extended by pushing or by a specialized instrument that provides suitable extension such as a gun-like or syringe-like plunger configuration.

[0022] In Figure 7d a cincture 709 like those described herein is advanced to the tissue opening using a second sheath 708. The cincture 709 and sheath can comprise an internal cincture or external cincture, both described elsewhere herein. The cincture 709 can be advanced from the second sheath 708, and tightened over the everted edges of the opening, as shown in Figure 7(e). The second sheath 708 can be removed, leaving the opening closed by the cincture 709, as shown in Figure 7(f). The gripper tines 702 can also be retracted into the gripper sheath 701, all as shown in Figure 7(f). The suture loop 706 (if required), gripper tines 702 and gripper sheath 701, and second sheath 708 can all be removed, leaving the cincture 709 in place closing the opening, as shown in Figure 7(g).

[0023] Figure 8 comprises schematic depictions of various embodiments of closure cinctures suitable for use in the present invention. Figure 8(1a) is a simple cincture with a slip-knot, with only one suture end to be pulled and distal loop for the pulling suture, Figure 8(1b) shows the cincture completely closed. Figure 8(2a) is a cincture with a slip knot device, with both suture ends to be pulled through the slip knot device, resulting in a loop of material when the cincture is completely closed, as shown in Figure 8(2b). Figure 8(3a) is a cincture composed of a loop and the pulling suture is functionally internal to the cincture initially, resulting in very little trailing material when the cincture is completely closed, as shown in Figure 8(3b). Figure 8(4a) demonstrates a cincture that closes by the use of dentates on the cincture so that it can lock when the cinture is closed, as shown in Figure 8(4b). Figure 8(5a) is a cincture made of multiple strands of material, resulting in a multiple level complex closed cincture, as shown in Figure 8(5b). Figure 8(6a) is a cincture with beads or other geometric structures or grippers that fit together and hold the wound closed with the cincture is closed, as shown in Figure 8(6b). Figure 8(7a) is a cincture made of memory material in the shape of an octagon, so that when pushed off the delivery sheath contracts to a four point star cincture, as shown in Figure 8(7b). Figure 8(8a) is a cincture made of a rubber-like or memory material, that when pushed off of the delivery sheath, contracts uniformly and closes the cincture, as shown in Figure 8(8b).

[0024] Examples of knots that can be suitable for use with the present invention include, but are not limited to, the overhand knot or half knot, the double overhand knot, the multifold-overhand-knot, the

Flemish eight, hitches (single simple, half, clove, two half, buntline, rolling Magnus, midshipmans tautline, adjustable jamming, cow, reversed half, lobster buoy), single loops (bowline, Dutch marine bowline, cowboy bowline, double figure-of-eight loop, flamish eight, bowstring knot, tucked double overhand, butterfly loop, lineman's loop, artillery loop, pendant hitch), clove hitch, reef knot, square knot, noose (simple noose, strangle-snare, scaffold knot , gallows knot, hangman's knot, reverse eight-noose), monkey fist, the dolly, fisherman's bend, surgeon's knot, sheet bend knot, timber hitch, fisherman's knot, reef knot, square knot, DuraKnot, sliding knots, simple sliding knot, Nicky's knot, Roeder's knot, Seoul Medical Centre knot, Smith & Nephew's knot, Tennesee's knot, purse string, and surgical knot with extra loop. Other knots and cincture devices could also be used and are anticipated. Endoscopic knot tying devices and suture cutting devices can also be used to create the cincture for this device and are also anticipated.

[0025] Examples of suture material at can be suitable for use with the present invention include, but are not limited to, absorbable, non-absorble, braided, monofilament, pseudo-monofilament, multfilament, barbed, smooth, directional, and bidirectional. The suture material can be composed of but not limited to polyglycolic acid, polydioxanon, polylactate, polycaprone, silk, linen, cotton, treated and non-treated collagen, "catgut", chromic, Vicryl, Monocyrl, PDS, polyesther, poypropylene, polyamide, stainless steel, and others.

[0026] The tines or gripping portion of a gripper sheath or components of sheath or cincture device can be made from any number of suitable materials, including radioopaque materials and materials coated to be made radioopaque, including bioabsorbable polymers or compounds, non-absorbable alloys and compounds including stainless steel, MP35, Nitinol, Nickel-Titanium ally, Kevlar, nylon polyester acrylic, gold, platinum, tantalum, niobium, molybdenum, rhodium, palladium silver, hafnium, tungsten, iridium. Materials with memory can be useful to allow tines to spontaneously open after extended from the sheath. These can be made in the form of wires, fibers, filaments, small beams, and other extruded, woven, or formed shapes. Piano wire, super elastic memory wire, chromium allows, alloys of titanium and nickel, and other elastic memory materials previously mentioned as well as others can be used as well The cincture device can be made from a number of suitable materials, including typical suture materials, flexible polymeric materials with elastomeric properties including polyurethane, polyethylene, polyestenurethane, polyimide, olyethreimide, polycarbonate, polysiloxane, polyvinyls, hydroxyethylmethacrylate, related polymers, co-polymers of these or other polymers, or drug-embedded or drug-eluting polymers to prevent coagulation or intimal hyperplasia (such as Taxol), also which can be made radioopaque by markers and addition of appropriate radiopaque materials.

Example Embodiments

[0027] The present invention can comprise a device to close puncture wounds caused by catheter procedures and especially angiography comprised cincture, snare, or noose-like device that introduction state resides in or on a sheath, and after either being expelled from the sheath or contracted spontaneously or by the use of a pulling suture loop, closes the cincture or noose, closing the wound. In order to allow the cincture to be placed, a gripping device is used that has tines that assumes a planar or conical or other shape, engages vessel wall by means of tissue hooks or penetrators, is pulled, and everts and holds the edges of the vessel wound or puncture so the the cincture can be placed.

[0028] The gripping device can have single or multiple hooks, arms, gripping members, or purchase or penetrating devices to engage and seize the vessel wall. Each hook or gripper can be a single or multiple hook, toothed, textured, penetrating, or gripping structure. The gripping device can have a minimal of 2 members (or tines) that are linear, curvilinear, spiral, leaf-like, diamond shaped, woven, or other complex shapes, but still function as an opening-closing structure that can be extended, grip the vessel wall, and then after the cincture is placed, be retracted.

[0029] The resident gripping device can have members that are coated or backed with a fabric or membrane, either completely or partially. The resident gripping device or cincture can elute therapeutic material to prevent thrombogenesis, hemorrhage, inflammation, and intimal hyperplasia with vascular closure. The device can be used in angiography, angioplasty, vascular puncture, tissue biopsy, or trauma that cause a puncture wound that should be closed. The gripping device or cincture can comprise materials with memory, so that the device spontaneously assumes it therapeutic shape when expelled from the sheath. The gripping device can comprise at least 2 or more members; 3 or more members can be preferable in some applications. The device can have members with angled dentates or tissue penetrators to prevent movement or migration of the device into the lumen of the blood vessel. These can also be used to retain the retaining lock.

[0030] A tissue opening can be closed according to the present invention by a) introducing a guidewire and then gripping sheath, b) penetrating the proximal surface of the blood vessel by the gripping sheath over the guidewire, c) gripping the blood vessel by extending the tines, d) putting a cincture delivery sheath over the gripping sheath, e) pulling gripping sheath against the tissue wall (e.g., the blood vessel wall), seating the grippers in the tissue and everting the wound edges, f) closing the cincture over the everted wound edges, g) removing the gripping tines and sheath, h) if no bleeding occurs, i) removing the guidewire, j) cutting the loop of string, leaving the cincture device safely seated on the external surface of the blood vessel with the puncture repaired. Alternatively, after the knot or cincture has been closed, the material or suture could be cut with an endoscopic suture cutter. Also, the guidewire could be removed before the gripping device, which would permit a tighter knot or cincture, and this is also anticipated.

[0031] A tissue opening can be closed according to the present invention employing a dedicated device consisting of gripping device, a sheath to deliver a cincture or knot device or knot tying device, placing the cincture over the gripping device and everted blood vessel wall, and closing the puncture wound with this cincture, noose-like device, or knot.

[0032] The particular sizes and equipment discussed above are cited merely to illustrate particular embodiments of the invention. It is contemplated that the use of the invention may involve components having different sizes and characteristics. It is intended that the scope of the invention be defined by the claims appended hereto.

Claims

We claim:

1) A tissue closure device, comprising:
   a) A delivery sheath;
   b) A cincture element, removably mounted with the delivery sheath, defining an opening within the cincture element that has a first size when the cincture element is mounted with the delivery sheath, and can assume a second size, smaller than the first, when the cincture element is no mounted with the delivery sheath.
2) A tissue closure device as in Claim 1, wherein the delivery sheath defines an inner cross section, and has a cincture-retaining structure near a first end of the delivery sheath, where the cincture element mounts with and is urged to the first size by the cincture-retaining structure.
3) A tissue closure device as in Claim 2, wherein the cincture-retaining structure comprises a ridge extending from the sheath into the inner cross section.
4) A tissue closure device as in Claim 2, further comprising a oneway fastener mounted with the cincture element, where the oneway fastener accommodates transition of the cincture element from the first size to the second size and resists transition of the cincture element from the second size to the first size.
5) A tissue closure device as in Claim 4, wherein the cincture element comprises a flexible elongated element, and wherein the oneway fastener comprises a slipknot tied in the elongated element.
6) A tissue closure device as in Claim 5, wherein the cincture element comprise a suture, line, string, or wire.
7) A tissue closure device as in Claim 1, wherein the delivery sheath defines an outer cross section near a first end thereof, wherein the cincture element mounts with the delivery sheath such that the first end delivery sheath mounts within the opening of the cincture element.
8) A tissue closure device as in Claim 7, wherein the delivery sheath comprises a cincture-retaining structure that discourages motion of the cincture element relative to the delivery sheath way from the first end of the delivery sheath.
9) A tissue closure device as in Claim 8, wherein the cincture-retaining structure comprises one or more elements mounted with or formed as part of the delivery sheath and extending beyond the outer cross section near the first end.
10) A tissue closure device as in Claim 7, further comprising a oneway fastener mounted with the cincture element, where the oneway fastener accommodates transition of the cincture element from the first size to the second size and resists transition of the cincture element from the second size to the first size.
11) A tissue closure device as in Claim 10, wherein the cincture element comprises a flexible elongated element, and wherein the oneway fastener comprises a slipknot tied in the elongated element.
12) A tissue closure device as in Claim 11, wherein the cincture element comprise a suture, line, string, or wire.

13) A tissue closure device as in Claim 1, wherein the cincture element assumes the second size absent an externally applied force, and wherein the delivery sheath supplies a sufficient force to the cincture element to maintain the cincture element in the first size while the cincture element is mounted with the delivery sheath.

14) A tissue closure device as in Claim 7, wherein the cincture element assumes the second size absent an externally applied force, and wherein the first end of the delivery sheath supplies a sufficient force to the cincture element to maintain the cincture element in the first size while the cincture element is mounted with the delivery sheath.

15) A method of closing an opening in tissue, comprising:

a) Everting the edges of the opening;

b) Placing a device as in Claim 1 proximal the everted edges;

c) Removing the cincture element from the delivery sheath such that the cincture element substantially surrounds the everted edges;

d) Causing the cincture element to assume the second size.

16) A method of closing an opening in tissue, comprising:

a) Everting the edges of the opening;

b) Placing a device as in Claim 7 proximal the everted edges;

c) Moving the delivery sheath and the cincture element relative to each other such that delivery sheath is not mounted within the cincture element and the everted edges are substantially within the cincture element;

d) Causing the cincture element to assume the second size.

17) A method as in Claim 15, wherein the cincture element comprises an elongated flexible structure having a oneway fastener mounted therewith, which fastener is operable from a second end of the delivery sheath, and wherein removing the cincture element from the delivery sheath and causing the cincture element to assume the second size comprises operating the oneway fastener.

18) A method as in Claim 17, wherein the oneway fastener comprises a slipknot.

19) A method as in Claim 16, wherein the cincture element comprises an elongated flexible structure having a oneway fastener mounted therewith, which fastener is operable from a second end of the delivery sheath, and wherein removing the cincture element from the delivery sheath and causing the cincture element to assume the second size comprises operating the oneway fastener.

20) A method as in Claim 19, wherein the oneway fastener comprises a slipknot.

21) A method as in Claim 19, wherein the oneway fastener mounts with a second elongated member that extends from the oneway fastener through a lumen interior to the delivery sheath to the second end of the delivery sheath.

22) A device as in Claim 1, wherein the delivery sheath comprises a lumen that can accommodate a gripping device and guidewire.

23) A device as in Claim 7, wherein the delivery sheath comprises a lumen that can accommodate a gripping device and guidewire.

24) A device as in Claim 1, further comprising a gripping device disposed within a lumen of the delivery sheath, wherein the gripping device comprises two or more gripping elements that grip and evert the edges of a tissue opening.

25) A device as in Claim 7, further comprising a gripping device disposed within a lumen of the delivery sheath, wherein the gripping device comprises two or more gripping elements that grip and evert the edges of a tissue opening.

Figure 1a

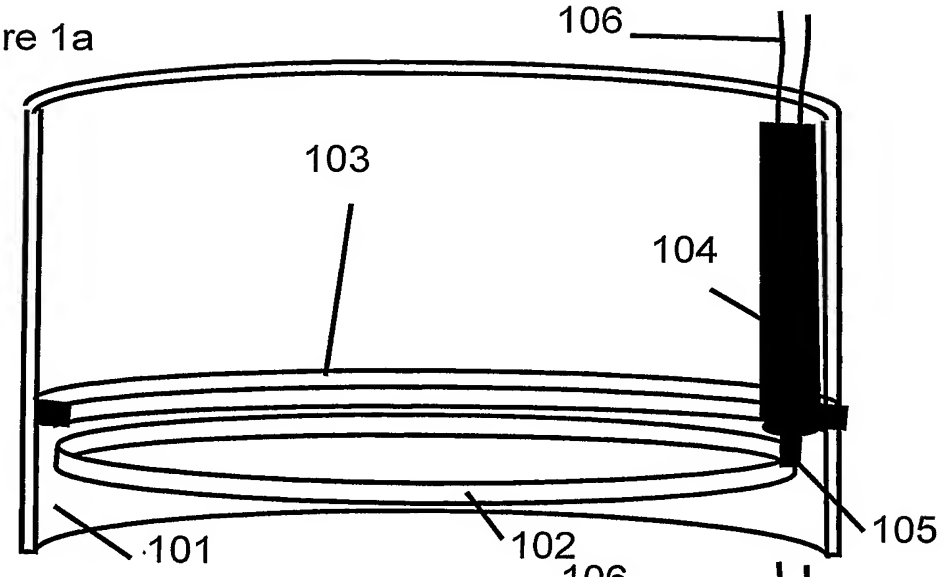


Figure 1b

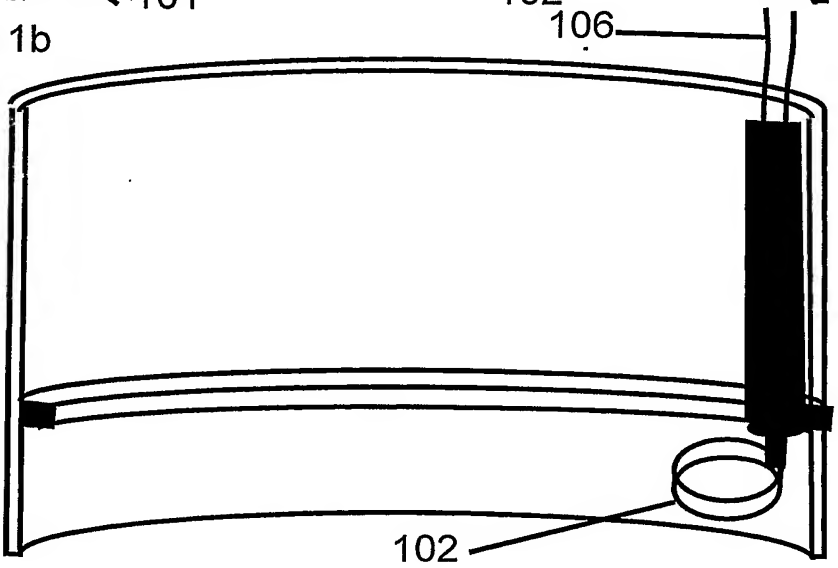


Figure 2a

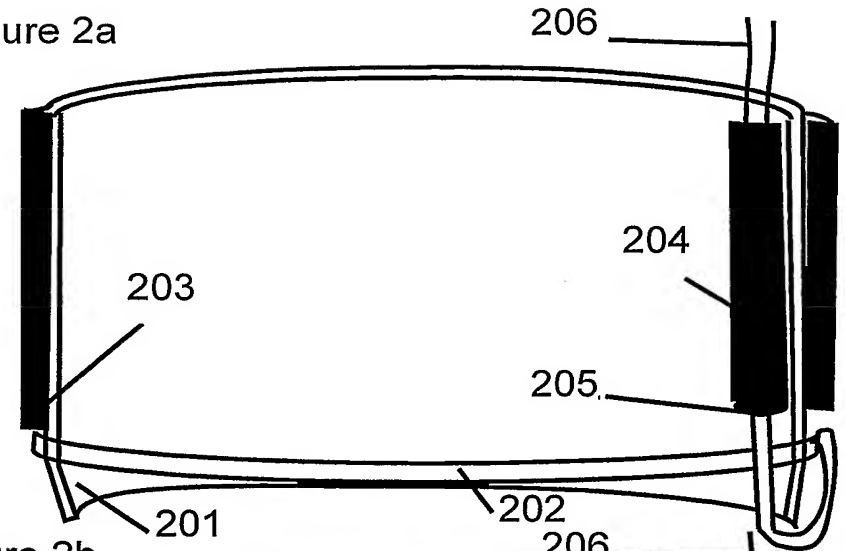


Figure 2b

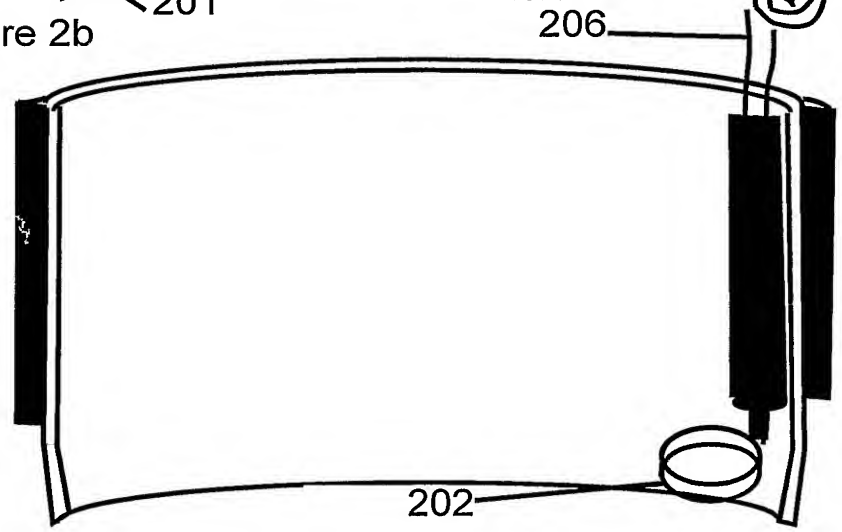


Figure 3a

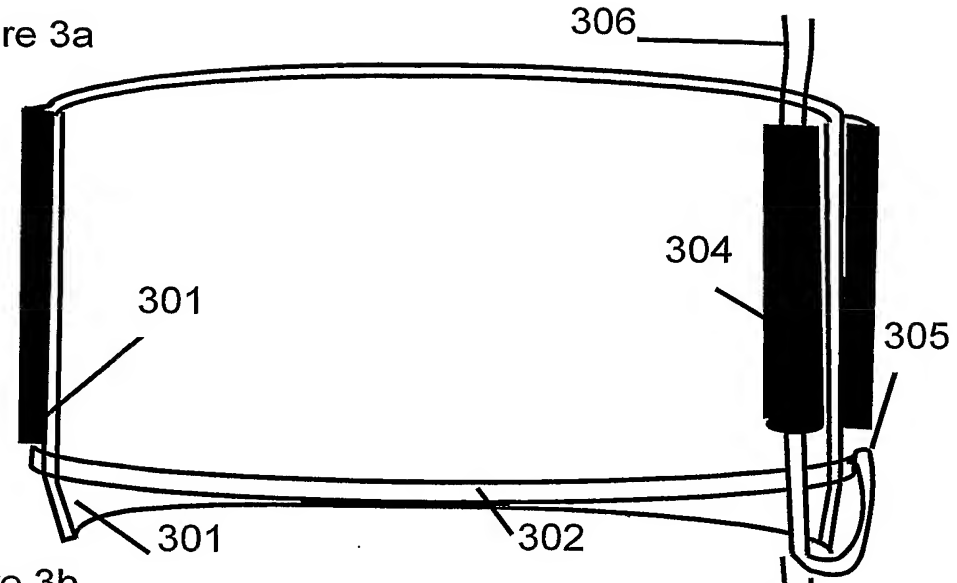
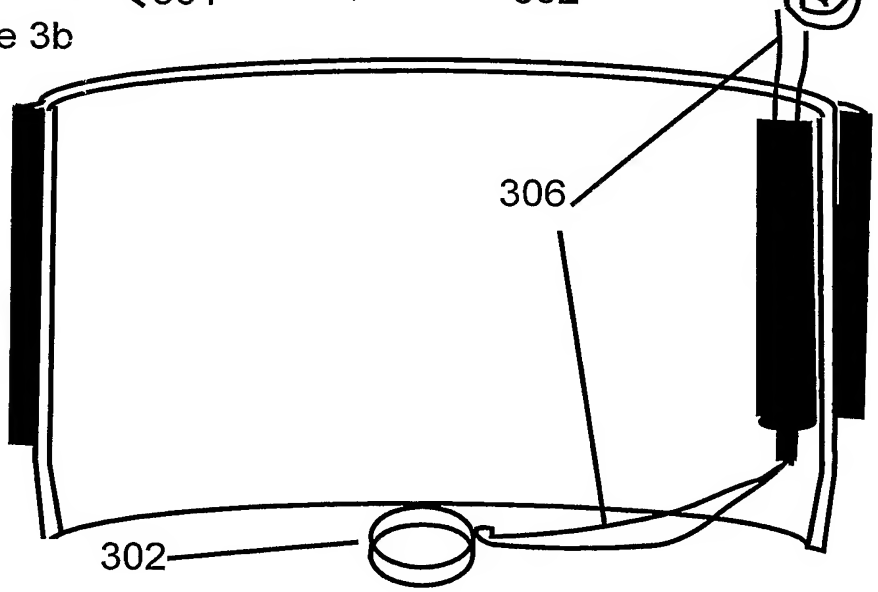


Figure 3b



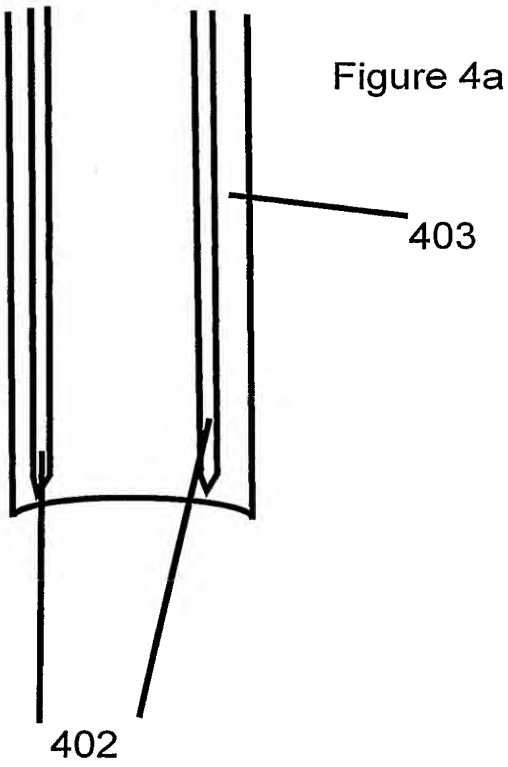


Figure 4a

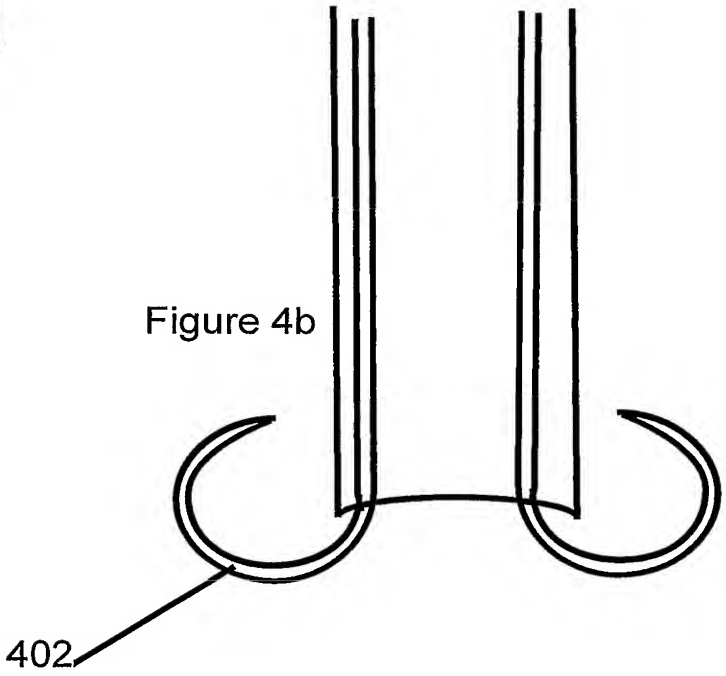


Figure 4b

Figure 5a

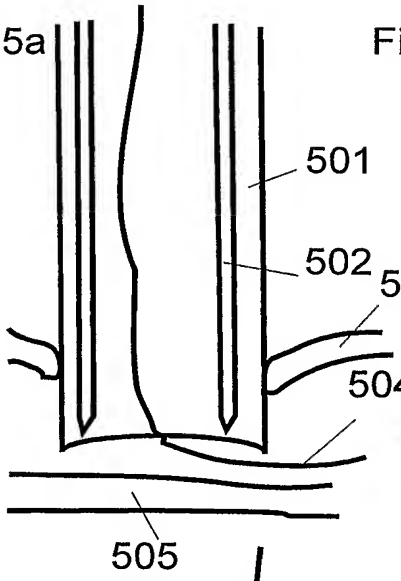


Figure 5b

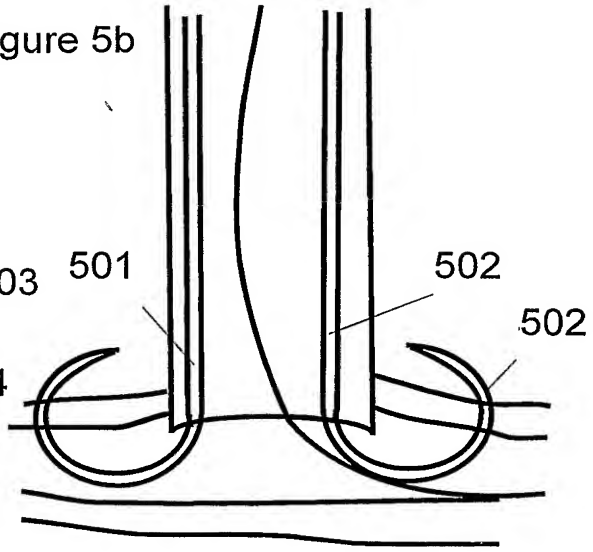


Figure 5c

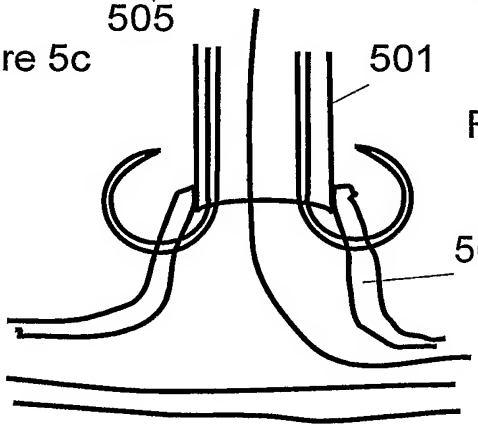


Figure 5d

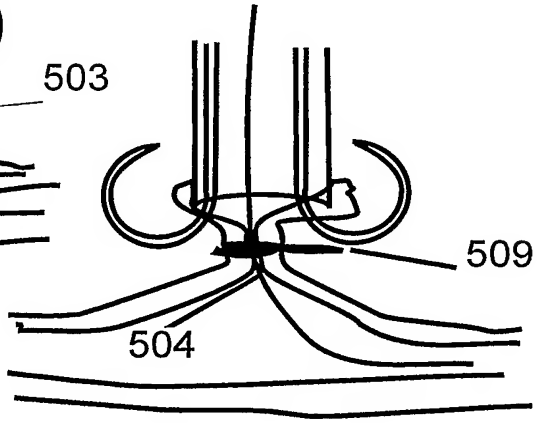


Figure 6a

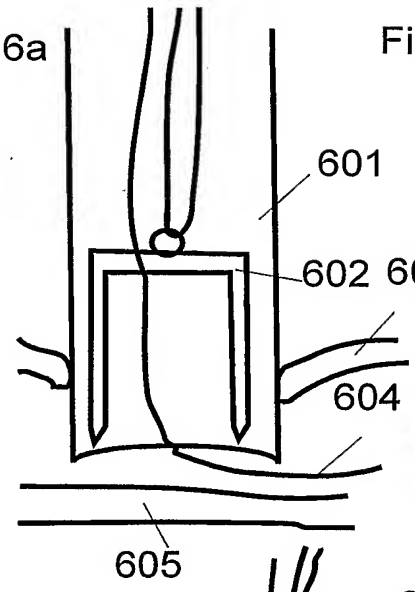


Figure 6b

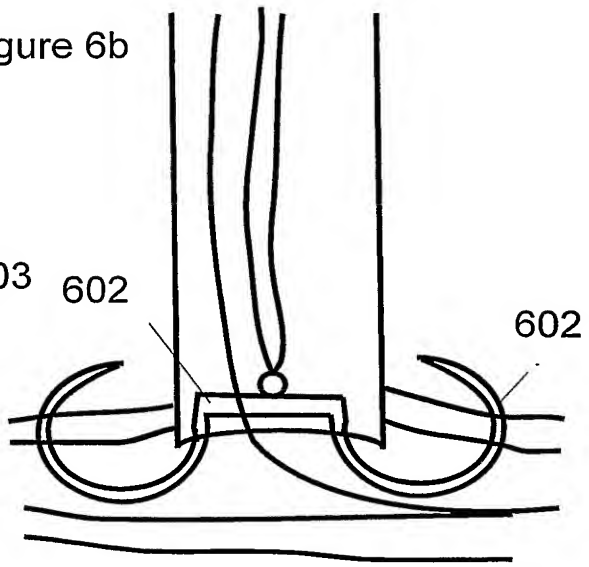


Figure 6c

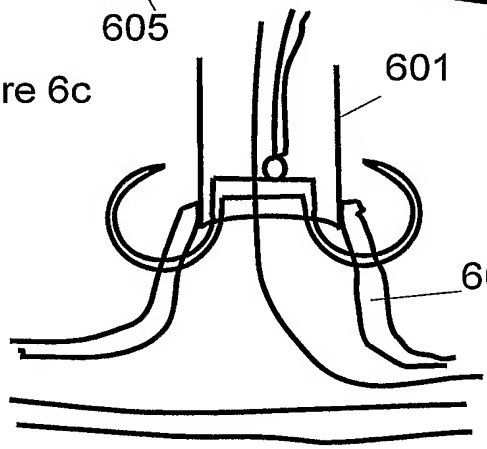


Figure 6d

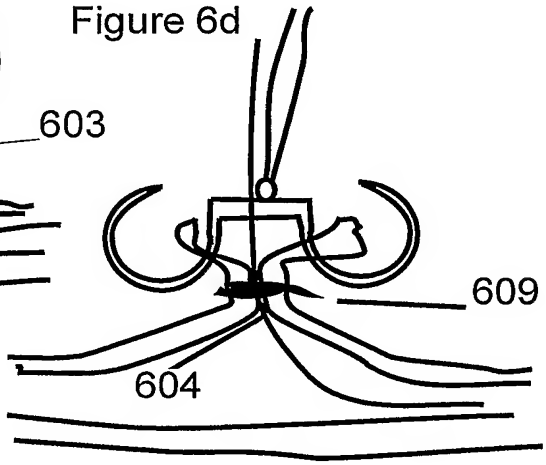


Figure 7a

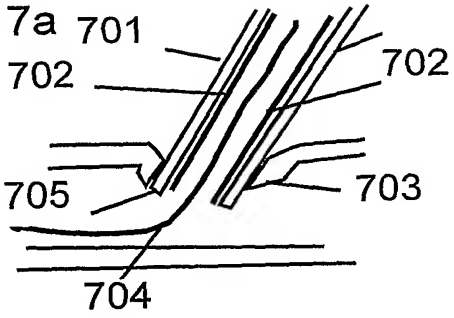


Figure 7b

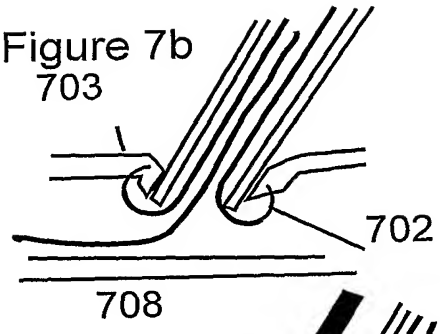


Figure 7c

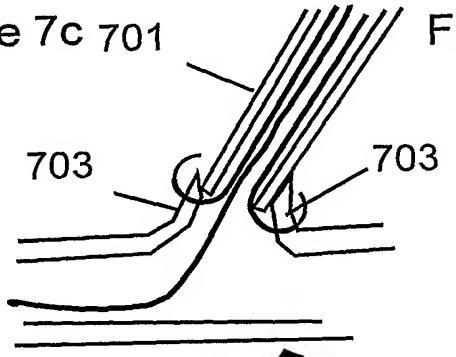


Figure 7d

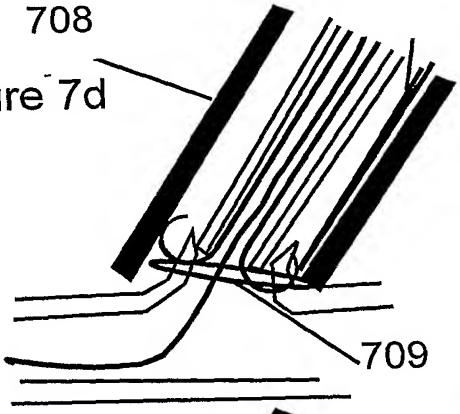


Figure 7e

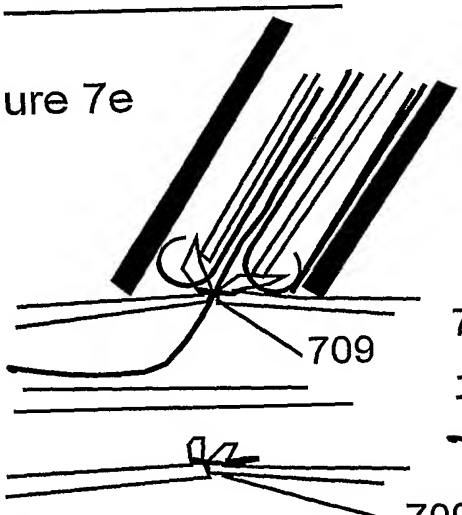


Figure 7f

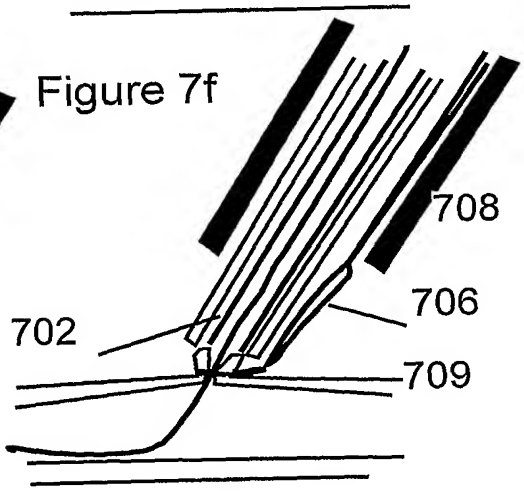


Figure 7g

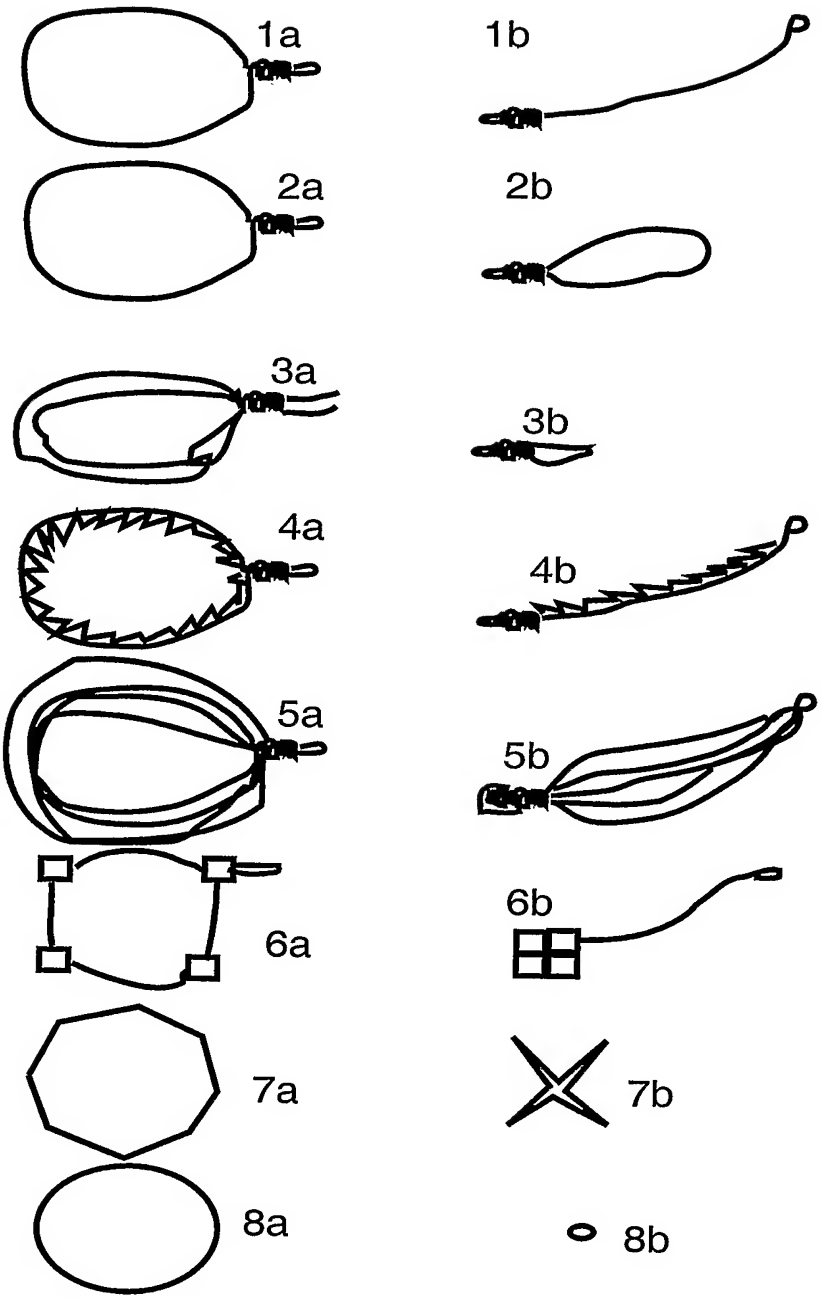


Figure 7

021287-0001300PC
CAR

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
V. GERALD GRAFE
P.O. BOX 2689
CORRALES, NM 87048

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing (*day/month/year*) 19 MAY 2008
Applicant's or agent's file reference 084-06-003	~~FOR FURTHER ACTION~~ See ~~paragraphs~~ 1 ~~and 4~~ below
International application No. PCT/US06/33031	International filing date (*day/month/year*) 24 August 2006 (24.08.2006)
Applicant SIBBITT,WILMER L.JR.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmittedherewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is ~~normally~~ two monthsfrom the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ ~~The applicant is hereby notified that no international search report~~ will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereonhas been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of**30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Jackie Ho Telephone No. (571) 272-3700

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
V. GERALD GRAFE
P.O. BOX 2689
CORRALES, NM 87048

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing (*day/month/year*) 19 MAY 2008
Applicant's or agent's file reference 084-06-003	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US06/33031	International filing date (*day/month/year*) 24 August 2006 (24.08.2006)
Applicant SIBBITT,WILMER L.JR.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmittedherewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two monthsfrom the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

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   ☐ the protest together with the decision thereonhas been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of**30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Jackie Ho Telephone No. (571) 272-3700

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 084-06-003	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below
International application No. PCT/US06/33031	International filing date (*day/month/year*) 24 August 2006 (24.08.2006)	(Earliest) Priority Date (*day/month/year*) 25 August 2005 (25.08.2005)
Applicant SIBBITT, WILMER L. JR.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 9 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed.
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 Rule 43.6 *bis(a)*
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/33031

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61B 17/04**(2006.01);**A61B 17/12**(2006.01)

USPC: 606/144
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/144, 113, 139, 145, 151, 157, 228

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,609,597 (LEHRER) 11 March 1997 (11.03.1997), figure 1-4, 6, 16-17, and 25, column 8 lines 10-45, column 15 lines 10-25, column 17-19	1-14, 22-25
X	US 6,572,629 B2 (KALLOO et al.) 3 June 2003 (03.06.2003), figure 2-5 and 9-12, column 4 lines 33-67, column 5-6	1-25

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the daimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
14 April 2008 (14.04.2008)

Date of mailing of the international search report
19 MAY 2008

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
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Authorized officer
Jackie Ho

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Form PCT/ISA/210 (second sheet) (April 2007)